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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,371	03/07/2001	Raymond Kaempfer	A34084 PCT USA-A	9946

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BAKER & BOTTS
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NEW YORK, NY 10112

EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/801,371

Applicant(s)

KAEMPFER ET AL.

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-20,22-31,47-49 and 51-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4-14,17,23-26,47,49 and 53 is/are allowed.
- 6) ☒ Claim(s) 15,16,18-20,48 and 52 is/are rejected.
- 7) ☒ Claim(s) 22,27,29-31 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Non-Final Rejection

Claims 1, 4-20, 22-31, 47-49, and 51-53 are pending.

Applicants' traversal, the amendment to claims 1, 4-9, 13, and 47-49, and the addition of claims 51-53 filed on 8/20/04 is acknowledged and considered.

Claim Objections

Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 depends on claim 14. Claim 14 is directed to the human TNF- α gene. Claim 22 recites inserting a cis-acting element into the intron of the human TNF- α gene. However, the human TNF-alpha gene already has a cis-acting nucleotide in an exon (3'UTR) of said gene but not in an intron. If the cis-acting element is inserted into an intron of the human TNF-alpha gene than it is no longer the human TNF-alpha gene. Thus, claim 22 does not further limit the subject matter of claim 14; it is outside its scope.

Applicant's arguments filed 8/20/04 have been fully considered but they are not persuasive because replacing "contained" with "inserted" in claim 13 altering the claim to "product by process" claim does not address the objection.

Claims 27 and 31 are objected to because the claim depends from claim 22.

Claim 29 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim: 1) cannot depend on multiple claims with different features, 2) cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Claim 29 depends from other multiple dependent claims, e.g., claim 23.

Claims 30 and 51 are objected to because the claims depend from claim 29.

Claim 48 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 49. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 15, 16, 18-20, 48 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 18 recite the limitation "said cis-acting element" in line 1 and lines 1-2, respectively. There is insufficient antecedent basis for this limitation in the claim.

Claims 16, 19 and 20 are rejected under 112 second paragraph because the claims depend from either claim 15 or claim 18.

Claims 48 and 52 recites the limitation "the cells" in step b). There is insufficient antecedent basis for this limitation in the claim. Suggest amending the phrase "transfecting a host cell with a DNA construct to give a host cell capable of expressing said protein wherein said" in step a) on lines 3 and 4 to recite: -- transfecting host cells with a DNA construct to give host cells capable of expressing said protein, wherein said --.

Claim 52 recites the limitation "culturing the cells obtained in (b)" in step c). There is insufficient antecedent basis for this limitation in the claim.

Conclusion

Claims 1, 4-14, 17, 23-26, 47, 49, and 53 are in condition for allowance because the claims are free of the prior of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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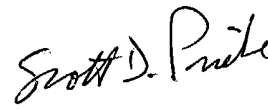
Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635


SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER